

Caregiver outcomes of the REACH-HF multicentre randomized controlled trial of home-based rehabilitation for heart failure with reduced ejection fraction

Wingham, Jennifer; Frost, Julia; Britten, Nicky; Greaves, Colin; Abraham, Charles; Warren, Fiona C; Jolly, Kate; Miles, Jackie; Paul, Kevin; Doherty, Patrick J; Singh, Sally; Davies, Russell; Noonan, Miriam; Dalal, Hasnain; Taylor, Rod S

DOI:

[10.1177/1474515119850011](https://doi.org/10.1177/1474515119850011)

License:

Creative Commons: Attribution-NonCommercial (CC BY-NC)

Document Version

Publisher's PDF, also known as Version of record

Citation for published version (Harvard):

Wingham, J, Frost, J, Britten, N, Greaves, C, Abraham, C, Warren, FC, Jolly, K, Miles, J, Paul, K, Doherty, PJ, Singh, S, Davies, R, Noonan, M, Dalal, H & Taylor, RS 2019, 'Caregiver outcomes of the REACH-HF multicentre randomized controlled trial of home-based rehabilitation for heart failure with reduced ejection fraction', *European Journal of Cardiovascular Nursing*, vol. 18, no. 7, pp. 611-620.
<https://doi.org/10.1177/1474515119850011>

[Link to publication on Research at Birmingham portal](#)

Publisher Rights Statement:

Checked for eligibility: 16/07/2019

Wingham, J., Frost, J., Britten, N., Greaves, C., Abraham, C., Warren, F. C., ... Taylor, R. S. (2019). Caregiver outcomes of the REACH-HF multicentre randomized controlled trial of home-based rehabilitation for heart failure with reduced ejection fraction. *European Journal of Cardiovascular Nursing*. <https://doi.org/10.1177/1474515119850011>

General rights

Unless a licence is specified above, all rights (including copyright and moral rights) in this document are retained by the authors and/or the copyright holders. The express permission of the copyright holder must be obtained for any use of this material other than for purposes permitted by law.

- Users may freely distribute the URL that is used to identify this publication.
- Users may download and/or print one copy of the publication from the University of Birmingham research portal for the purpose of private study or non-commercial research.
- User may use extracts from the document in line with the concept of 'fair dealing' under the Copyright, Designs and Patents Act 1988 (?)
- Users may not further distribute the material nor use it for the purposes of commercial gain.

Where a licence is displayed above, please note the terms and conditions of the licence govern your use of this document.

When citing, please reference the published version.

Take down policy

While the University of Birmingham exercises care and attention in making items available there are rare occasions when an item has been uploaded in error or has been deemed to be commercially or otherwise sensitive.

If you believe that this is the case for this document, please contact UBIRA@lists.bham.ac.uk providing details and we will remove access to the work immediately and investigate.

Caregiver outcomes of the REACH-HF multicentre randomized controlled trial of home-based rehabilitation for heart failure with reduced ejection fraction

European Journal of Cardiovascular Nursing
1–10

© The European Society of Cardiology 2019



Article reuse guidelines:

sagepub.com/journals-permissions

DOI: 10.1177/1474515119850011

journals.sagepub.com/home/cnu

Jennifer Wingham¹, Julia Frost², Nicky Britten², Colin Greaves³, Charles Abraham², Fiona C Warren², Kate Jolly³, Jackie Miles⁴, Kevin Paul⁵, Patrick J Doherty⁶, Sally Singh⁷, Russell Davies⁸, Miriam Noonan², Hasnain Dalal^{2,9} and Rod S Taylor^{2,10}
on behalf of the REACH-HF research group.

Abstract

Background: Caregivers frequently provide support to people living with long-term conditions. However, there is paucity of evidence of interventions that support caregivers in their role. Rehabilitation EnAblement in Chronic Heart Failure (REACH-HF) is a novel home-based, health-professional-facilitated, self-management programme for patients with heart failure (HF) and their caregivers.

Methods: Based on the random allocation of individual adult patients with reduced ejection fraction (HFrEF) and left ventricular ejection fraction <45% within the past five years, the caregiver of patients was allocated to receive the REACH-HF intervention over 12 weeks (REACH-HF group) or not (control group). Caregiver outcomes were generic health-related quality of life (EQ-5D-5L), Family Caregiver Quality of Life Scale questionnaire (FamQoL), Caregiver Burden Questionnaire HF (CBQ-HF), Caregiver Contribution to Self-care of HF Index questionnaire (CC-SCHF) and Hospital Anxiety and Depression Scale (HADS). Outcomes were compared between groups at 4, 6 and 12 months follow-up. Twenty caregivers receiving REACH-HF were purposively selected for qualitative interviews at 4 and 12 months.

Results: Compared with controls (44 caregivers), the REACH-HF group (53 caregivers) had a higher mean CC-SCHF confidence score at 12 months (57.5 vs 62.8, adjusted mean difference: 9.3, 95% confidence interval: 1.8–16.8, $p = 0.016$). No significant between group differences were seen in other caregiver outcomes. Qualitative interviews showed that most caregivers who received the REACH-HF intervention made positive changes to how they supported the HF patient they were caring for, and perceived that they had increased their confidence in the caregiver role over time.

Conclusion: Provision of the REACH-HF intervention for caregivers of HF patients improved their confidence of self-management and was perceived for some to be helpful in supporting their caregiver role.

Keywords

Heart failure, caregiver, cardiac rehabilitation self-management, home-based programme

Date received: 23 February 2019; revised: 17 April 2019; accepted: 18 April 2019

¹Primary Care Research Group, University of Exeter Medical School, UK

²Institute of Health Research, University of Exeter Medical School, UK

³Institute of Applied Health Research, University of Birmingham, UK

⁴Anuerin Bevan University Health Board, Research and Development, Abergavenny, UK

⁵REACH-HF Patient and Public Involvement Group, c/o Royal Cornwall Hospitals NHS Trust, UK

⁶National Audit of Cardiac Rehabilitation, University of York, UK

⁷University Hospitals of Leicester NHS Trust, UK

⁸Sandwell & West Birmingham Hospitals NHS Trust, Birmingham, UK

⁹Royal Cornwall Hospitals NHS Trust, Truro, UK

¹⁰Institute of Health and Well Being, University of Glasgow, UK

Corresponding author:

Rod Taylor, Institute of Health and Well Being, MRC/CSO Social and Public Health Sciences Unit, University of Glasgow, Top floor, 200 Renfield Street, Glasgow, G2 3AX, Scotland, UK.

Email: rod.taylor@gla.ac.uk

Introduction

Heart failure (HF) is an unpredictable life-limiting condition that is challenging to self-manage. People with HF typically experience poor levels of health-related quality of life (HRQoL) due to episodes of breathlessness, oedema, fatigue and associated anxiety and depression.¹ Families and social networks frequently support people living with long-term conditions, including HF.^{2,3} Caregivers for people with HF have identified three distinct needs: (1) supporting HF management, including coping with the variability of HF symptoms, understanding and managing medicines, providing emotional support, promoting exercise and physical activity; (2) developing the caregiver role, including communicating with health professionals, managing their own well-being; and (3) developing skills to engage social support, and voluntary and services while recognizing that the long-term future may be uncertain.^{4,5} However, there is currently a paucity of evidence on interventions that support caregivers of people with HF in their role.⁶⁻⁹

Home-based programmes can widen access to cardiac rehabilitation (CR) and have been shown to be as effective as centre-based models for people after myocardial infarction and coronary revascularisation.^{10,11} Moreover, home-based programmes also have greater potential to involve the caregivers in the rehabilitation process and offer them support. Rehabilitation EnAblement in Chronic Heart Failure (REACH-HF) is a *de novo* rehabilitation self-management programme for patients with HF and their caregivers. The REACH-HF intervention is novel in a number of ways: (1) theory-based; (2) co-developed with stakeholders (patients, caregivers, clinicians, service providers); (3) based on intervention mapping; (4) delivered in home-based setting (in contrast to the traditional hospital/centre-based venue) by trained health professionals; and (5) directed at both patients with HF and their caregivers.¹²⁻¹⁴

A multicentre randomized controlled trial has shown that, compared to usual care alone, the addition of the REACH-HF intervention improves the disease-specific HRQoL of people with HF with reduced ejection fraction (HFrEF) and is a cost-effective use of healthcare resources.^{15,16} The aims of this paper are twofold: first, to compare the caregiver outcomes between the REACH-HF and control groups; second, to report the views and perceptions of caregivers on their experience of using the REACH-HF intervention.

Methods

Study design

The published protocol provides a full description of the trial design and procedures.¹² In summary, men and women aged ≥ 18 years with a confirmed diagnosis of HFrEF on echocardiography or angiography (i.e. left ventricular

ejection fraction $<45\%$ within the preceding five years) were recruited from primary and secondary care settings in four centres in the United Kingdom (Birmingham, Cornwall, Gwent and York). At study entry, patients were asked to nominate if they had a caregiver, i.e. a spouse, other relative or friend, who provides unpaid support to patients. Unpaid support includes emotional support, prompting with taking medications, observing for signs and symptoms of HF, getting prescriptions, encouraging participation in social events and physical activity, helping with household tasks or providing physical care.

Patients were randomly allocated in a 1:1 ratio, stratified by investigator site and baseline plasma N-terminal proB-type natriuretic peptide levels (≤ 2000 vs >2000 pg/ml), using minimization to facilitate balance between the groups. Randomization numbers were computer generated and assigned in strict sequence at the point of randomization. To maintain concealment, the Peninsula Clinical Trials Unit used a password-protected, Web-based randomization system to allocate participants after consent was obtained and baseline assessment data entered. Caregivers were allocated to receive the REACH-HF intervention (REACH-HF group) or not (control group) in accord with the random allocation of their patient partner.

The investigation conformed to the principles outlined in the Declaration of Helsinki and was approved by the North West Lancaster Research Ethics Committee (14/NW/1351). Written informed consent was obtained from both patient and caregiver participants.

REACH-HF intervention

A detailed description of the REACH-HF intervention, its development including extensive consultation and involvement of our patient and public involvement group and its theoretical underpinnings is published elsewhere.¹⁴

The REACH-HF intervention is a comprehensive, evidence-informed, patient-centred, theory-based, self-care support programme that includes four core elements:^{12,14,15}

- 'REACH-HF manual' – providing information on: (1) understanding HF, (2) managing HF in terms of including change of lifestyle key self-care targets (building physical fitness through exercise, managing fluids, managing medications and managing stress/anxiety/low mood) and (3) living with the uncertainty of HF.
- 'Progress tracker' – allows patients to record symptoms, physical activity and other actions related to self-care; this was designed to act as a 'scaffold' to aid reflection on progress, increase their understanding of how self-care actions affect their physical and mental wellbeing, and adapt their self-care strategies over time.

- ‘Family and friends resource’ – for use by caregivers, including advice on providing support, becoming a caregiver, managing the caregiver’s own health and wellbeing and getting help.
- Facilitation by cardiac nurses or physiotherapists, including assessment of individual patient and caregiver needs and concerns and tailoring of the intervention content to address these; this element was supported by a three-day training course for facilitators on how to deliver the intervention using a patient-centred style of communication.

The intervention was delivered at the patient’s home via a mixture of face-to-face and telephone contacts over 12 weeks (typically 4–6 contacts). During home visits and telephone follow-up, facilitators supported the participants and caregivers to understand and manage HF, set goals and develop self-care strategies.¹⁵ Facilitators were asked to spend time with the caregivers to help them understand how best to support the patient, as well as to look after their own wellbeing.

Outcomes and interviews

Caregiver outcomes included the Hospital Anxiety and Depression scale (HADS),¹⁷ generic HRQoL (EQ-5D-5L questionnaire),¹⁸ Family Caregiver Quality of Life (FamQoL),¹⁹ Caregiver Burden Questionnaire for Heart Failure (CBQ-HF),²⁰ and Caregiver’s Contribution to Self-care of HF Index (CC-SCHFI).²¹ Outcome data were collected during three clinic visits at baseline, four and 12 months, and by postal questionnaire at six months. At the baseline clinic visit, sociodemographic data was also collected. Data was collected by research nurses who were blinded to group allocation.

Twenty caregivers in the REACH-HF group were selected for interview at 4 and 12 months using maximal variation sampling that took account of patient and caregiver baseline HRQoL scores, caregiver demographics (age, gender and ethnicity), and geographical location. Home interviews were conducted by two experienced qualitative researchers (JW, Lucy Moore). Caregivers were encouraged to describe their views and experiences of the REACH-HF intervention. Interviewers were guided by answers from the interviewees and used further probing questions such as ‘tell me more about ...?’ Other techniques to enhance the interview included reflecting on what was said and using non-verbal communication to show that the researcher was actively listening. Interviewers summarized the content of the interview at the end of the discussion and invited the participant to add anything else they wanted to share. The interview topic guide (Supplementary table 1) was reviewed throughout the study so that the questions were informed by relevant emerging topics, e.g. the impact of roles outside the home

and the difficulties encountered by caregivers who did not live with the cared for person. Interviews were audio recorded and researchers wrote field notes at the end of each interview detailing observations of the home and social context; reflections on researcher performance and potential influence on the interview; how the participant responded to the questions; and initial thoughts about the main points arising from the interview.

Data analysis

The sample size of the study was based on a minimal clinically important difference (5 points) in the HF patient primary outcome measure (Minnesota Living with Heart Failure Questionnaire) and assumed attrition rate of 10%. At type I error of 0.05 and power of 90% this required a total of 108 patients per group were required. There was no formal sample size calculation for the number of caregivers participating in this study.

Quantitative analysis. All statistical analyses were conducted to a predefined analysis plan agreed in advance with the trial management group, Trial Steering committee and Data Management committee. Caregiver outcomes are reported descriptively by group at all assessment points (baseline, and 4 and 12 months follow-up). REACH-HF and control group caregiver outcomes are compared at 12-months using linear regression methods, adjusting for baseline score. All between-group outcome comparisons are presented intention-to-treat basis (i.e. according to group allocation at baseline) in caregivers with complete outcome data at 12 months and are reported as mean differences with a 95% confidence interval (CI). No imputation for missing data was undertaken. Analyses were undertaken by the trial statistician (FCW) who was blinded to group allocation and according to a predefined analysis plan using Stata version 14.1. No interim analyses were performed.

Qualitative analysis. A thematic analysis was conducted by two experienced qualitative researchers (JW and JF).²¹ Interview audio tapes were transcribed verbatim. The data set included: facilitator contact sheets, baseline questionnaire data, field notes, and interview transcripts. Data was managed by NVIVO 11 Pro. Sections of data related to the aims were assigned a code that summarized the content either descriptively or interpretively. Codes with common features were grouped together in emerging themes, before finally being assigned to overarching, interpretive themes. Constant comparative techniques were used to compare individual 4- and 12-month interviews and across all caregiver participants’ interviews.²² An additional analytical memo note was used to note and test early hypotheses and explore emergent hypotheses from the data.

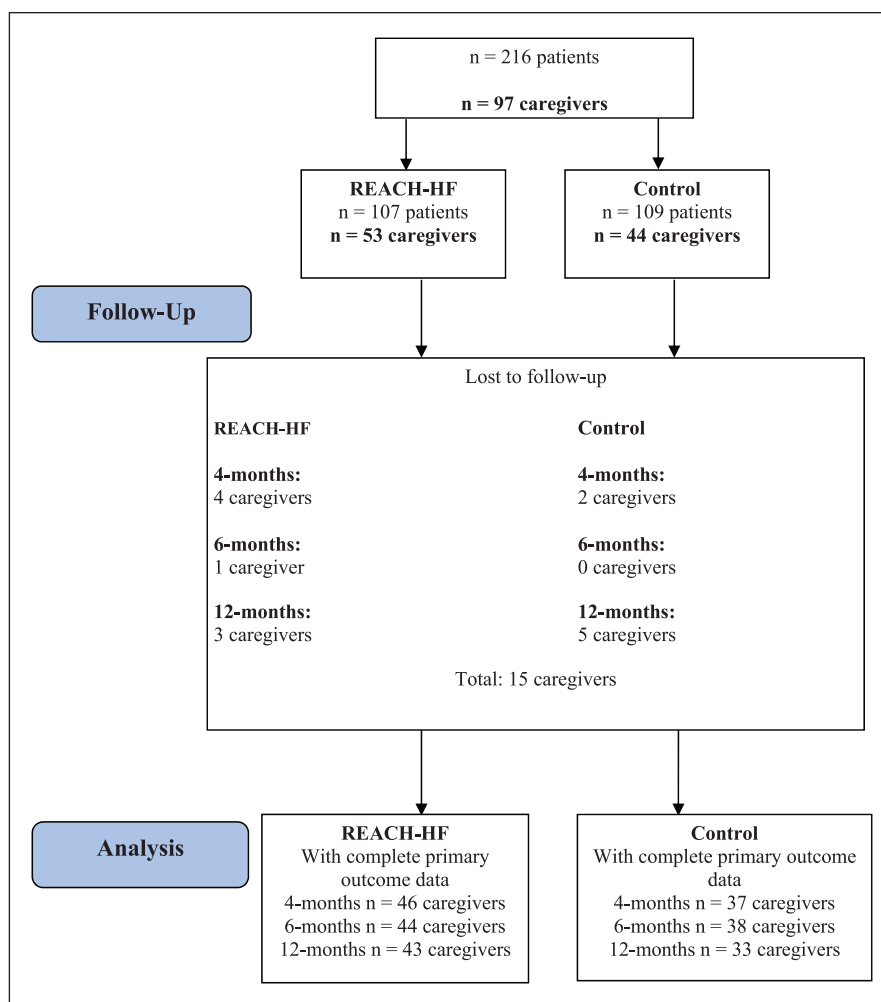


Figure 1. CONSORT flow diagram.

Results

Study sample

Between January 2015 and February 2016, 216 HFrEF patients were randomly allocated to the REACH-HF group ($n = 107$) and control group ($n = 109$). A total of 97 patients declared a caregiver - 53 caregivers in the REACH-HF and 44 in the control group. At 12 months, outcomes data was available from 45 (85%) caregivers in the REACH-HF group and 37 controls (84%) (see Figure 1).

Baseline characteristics

Caregivers were typically the partner or direct relative, were of a younger mean age than participating patients and predominantly female. There was evidence of imbalance in caregiver baseline demographic characteristics and outcome scores between groups; controls were older and had higher levels of depression and anxiety and lower generic HRQoL (Tables 1 and 2).

Outcomes

There was evidence of improvements from baseline at 4, 6 and 12 months follow-up in a number of caregiver outcomes in the REACH-HF group, including HADS-anxiety, CBQ-HF physical, social life and lifestyle and all SCHFI dimension scores. Compared to controls, the only significant difference was in mean CC-SCHFI confidence score at 12-months (57.5 vs 62.8, adjusted mean difference: 9.3, 95% CI: 1.8–16.8, $p = 0.016$). Table 2 shows the outcome means and standard deviations in both groups.

Interviews

One caregiver declined to be audio recorded and was excluded from the analysis. The 19 caregivers who agreed to be interviewed had similar demographic characteristics to the overall study cohort of caregivers (Supplementary table 2). All 19 caregivers were interviewed at four months and 16 were interviewed at 12 months (one withdrew as her husband was unwell and two declined to take part). The majority of interviews were conducted in the patient's

Table 1. Characteristics of caregivers and HF patients they care for.

	REACH-HF group (n = 53)	Control group (n = 44)
Caregivers		
Gender: female, n (%)	43 (81)	33 (75)
Age: years, mean (SD)	62.8 (14.7)	68.2 (11.3)
Relationship to patient: n (%)		
Spouse/partner	44 (83)	36 (82)
Direct family	5 (9)	6 (14)
Other relative	1 (2)	1 (2)
Friend	3 (6)	1 (2)
Employment status: n (%)		
Employment/self-employment	15 (28)	6 (14)
Retired	35 (66)	33 (75)
Housework	2 (4)	0 (0)
Unemployed	1 (2)	3 (7)
Other	0 (0)	2 (5)
Location: n (%)		
Birmingham	6 (11)	8 (18)
Cornwall	19 (36)	14 (32)
South Wales	13 (25)	10 (23)
York	15 (28)	12 (27)
Patients^a		
Gender: female, n (%)	13 (25)	9 (20)
Age: years, mean (SD)	69.4 (10.9)	71.3 (10.3)
Employment status: n (%)		
Employment/self-employment	7 (13)	3 (7)
Retired	43 (81)	36 (82)
Housework	0 (0)	1 (2)
Unemployed	2 (4)	1 (2)
Other	1 (2)	3 (7)
Living alone, n (%)	6 (11)	3 (7)
NYHA: n (%)		
Class I	11 (21)	8 (18)
Class II	29 (55)	25 (57)
Class III	13 (25)	11 (25)
Class IV	0 (0)	0 (0)
Ejection fraction: mean (SD), n	31.0 (8.8), 40	31.3 (8.6), 34

^aDemographic and clinical characteristics of HF patients with caregivers.

home (usually with the patient present) and the average duration of interviews was 51 min (range 15–103) and 43 min (range 13–100) at 4 and 12 months respectively.

Two overarching themes emerged from interviews: (1) engagement with the REACH-HF intervention and (2) impact on caregiver role. These themes and related sub-themes are described below.

Theme 1: engagement with the REACH-HF intervention

Expectations. and hope

Most caregivers spoke of hope that the cared for person would make changes in lifestyle or have professional guidance on how best to manage HF and what to do in an emergency.

My goal is that he keeps it [heart failure] off, and keeps himself healthy, because we have discussed the only alternative. That if he's unable to look after my mum, the most horrendous thing that could happen to them both is that mum has to be put in a home or something like that, and he can't bear that.

(Male caregiver – son, aged 49 years)

Few caregivers had expectations for their own health and wellbeing but most expressed feeling valued as they were included in the intervention.

Engagement with the intervention. While many caregivers did engage with the intervention, there was evidence that some caregivers actively chose to not engage with the

Table 2. Caregiver reported outcomes at baseline and follow-up. Data are means (SD, n) unless otherwise indicated.

Outcome (possible range of scores: best to worst)	Baseline		4 months		6 months		12 months		Between group difference ^a Mean (95% CI), p-value
	REACH-HF Mean (SD) N	Control Mean (SD) N	REACH-HF Mean (SD) N	Control Mean (SD) N	REACH-HF Mean (SD) N	Control Mean (SD) N	REACH-HF Mean (SD) N	Control Mean (SD) N	
HADS anxiety (0–21)	6.3 (4.6), 53	7.6 (4.0), 44	5.5 (4.9), 46	6.8 (4.0), 36	5.1 (4.8), 43	6.2 (3.8), 38	5.3 (5.2), 43	6.1 (3.8), 33	0.0 (–1.4 to 1.4), 0.979
HADS depression (0–21)	3.3 (3.2), 53	4.0 (3.0), 44	3.0 (3.5), 46	2.5 (2.6), 36	2.8 (3.3), 43	3.8 (3.1), 38	3.1 (3.4), 43	2.8 (2.8), 33	0.7 (–0.2 to 1.6), 0.130
Fam-Qol overall (80 to 16)	59.7 (9.9), 53	59.9 (8.9), 44	62.4 (10.9), 45	65.1 (10.7), 37	61.3 (10.2), 44	61.2 (8.8), 38	60.5 (10.4), 43	61.5 (10.6), 33	0.1 (–3.8 to 4.0), 0.971
Fam-Qol physical (20 to 4)	16.4 (3.0), 53	16.8 (2.6), 44	16.9 (3), 45	17.7 (2.3), 37	16.5 (2.8), 44	16.7 (2.4), 38	16.5 (3.2), 43	16.2 (2.9), 33	0.9 (–0.3 to 2.0), 0.139
Fam-Qol psychological (20 to 4)	14.2 (4.5), 53	13.7 (3.8), 44	15.3 (4.4), 45	15.7 (4.2), 37	14.9 (4.2), 44	14.4 (3.1), 38	14.9 (4.3), 43	15 (4.0), 33	–0.1 (–1.5 to 1.4), 0.939
Fam-Qol social life (20 to 4)	16.6 (3.1), 52	15.5 (3.8), 44	16.9 (3.3), 45	17.2 (3.0), 37	16.3 (3.1), 44	15.9 (3.0), 38	16.5 (3.2), 43	16.2 (3.6), 33	–0.2 (–1.5 to 1.2), 0.810
CBQ-HF physical (0–20)	3.8 (4.4), 53	3.6 (4.4), 44	2.8 (3.9), 46	2.4 (3.2), 37	2.7 (3.2), 44	3.4 (3.7), 38	2.7 (3.6), 43	3.6 (4.5), 33	–1.0 (–2.5 to 0.5), 0.191
CBQ-HF emotional (0–60)	15.6 (12.4), 53	16.0 (10.9), 44	14.3 (10.7), 46	12.5 (11.2), 37	14.0 (9.9), 44	14.7 (10.6), 38	13.7 (10.6), 43	13.6 (10.9), 33	–0.7 (–4.6 to 3.1), 0.700
CBQ-HF social life (0–8)	1.4 (1.9), 53	0.9 (1.5), 44	0.8 (1.2), 46	0.6 (1.3), 37	1.1 (1.5), 43	1.1 (1.9), 37	0.9 (1.3), 43	1.2 (1.6), 33	–0.6 (–1.1 to 0.0), 0.058
CBQ-HF lifestyle (0–16)	3.4 (4.4), 53	3.0 (3.1), 44	2.3 (2.9), 46	3.0 (3.5), 37	2.4 (2.9), 44	3.6 (4.1), 37	2.3 (3.2), 43	2.8 (3.4), 33	–0.7 (–1.9 to 0.5), 0.244
EQ-5D-5L (0.00–1.00)	0.828 (0.186), 53	0.797 (0.147), 44	0.847 (0.166), 46	0.798 (0.202), 36	0.828 (0.147), 44	0.783 (0.158), 36	0.825 (0.150), 42	0.776 (0.188), 33	0.021 (–0.057 to 0.098), 0.599
CC-SCHF maintenance (0–100)	36.5 (21.6), 53	42.7 (20.3), 44	42.9 (25.5), 46	42.0 (20.6), 37	43.8 (22.7), 44	41.0 (20.6), 37	42.2 (24.8), 43	39.8 (20.5), 33	7.3 (–1.6 to 16.2), 0.108
CC-SCHF management ^b maintenance (0–100)	39.0 (21.9), 24	45.2 (17.9), 21	52.7 (19.7), 11	49.7 (14.8), 15	44.7 (22.4), 17	42.5 (22.5), 16	50.5 (23.2), 20	52.5 (24.9), 16	8.9 (–14.1 to 31.9), 0.419
CC-SCHF confidence maintenance (0–100)	55.3 (24.0), 53	51.8 (24.8), 44	57.9 (23.0), 45	56.8 (25.4), 37	58.8 (22.5), 41	57.5 (21.7), 38	62.8 (21.9), 43	50.8 (24.9), 33	9.3 (1.8–16.8), 0.016

^aMean differences adjust for baseline values.^bParticipants excluded if at least one missing value.

facilitator and obstructed facilitator efforts to engage. Proactive engagement was enhanced when the patient made perceived improvements in HRQoL, especially if there was an improvement in social activities. These engaged caregivers were also more likely to have a wider close social support network, and there are examples where the ‘family and friends resource’ as shared with this social network. Conversely, fear of hospitalization of the cared for person could also act a factor motivating active engagement.

The manual was on the table and shows signs of wear and has post it notes on it. She has from time to time looked at it for referral and comfort. She could not recall a specific example but the look of the manual shows someone is using it. The Family and Friends resource also had book marked sections – symptoms and what to do in an emergency and when to call for help. There was a sense of being prepared for an emergency which I reflected back to her and she agreed.

(Field notes: Female caregiver – wife aged 74)

Factors influencing non-engagement or limited/passive engagement. Those caregivers who had a good relationship with an existing nurse or health professional were less likely to see the need for the intervention or to understand that the intervention could be used to address their own health and wellbeing. Employed caregivers had no or little facilitator contact. One facilitator attempted on multiple occasions to contact a caregiver but the caregiver did not return the calls, and this obstructed engagement. Non-engaged caregivers often felt they already had the knowledge and skills they required.

When [wife] went for consultations at the hospital or with the [surgeon], with the doctors and everything, generally I was there. So I knew what they [facilitator] had to say and what their opinions generally were. And we had information anyway about the heart conditions because we get this, (British) Heart Foundation magazine, which is really quite interesting. I'm not really a novice in the game if you like and haven't been really from the start.

(Male caregiver – husband, aged 84)

Resource use. All sections of the REACH-HF family and friends' resource were used by at least one caregiver and the most used sections related to managing signs and symptoms, what to do in an emergency and when to call for help.

I think there's – in there there's a website for um carers ... and you think 'Well, hang on a minute, yeah, there are other people out there and they all understand exactly how you feel'. Isolated, I suppose, that's the word, I don't feel so isolated anymore.

Impact of research processes. An unexpected finding was the significance of the caregiver questionnaires used

to collect baseline quantitative outcome data in the trial research nurse appointments. The HADS and HRQoL outcome questionnaires acted as a ‘stop and think’ moment to reflect for the first time on the impact of being caregivers. Some reported that as a result they were more honest when completing the questionnaire at the follow-up data collection points.

It was bang on the money but there was no reference to that throughout the... [Intervention]. Throughout the study. If that was, if that could be a constructive criticism.But that questionnaire was perfect.

(Male caregiver – husband aged 45)

Theme 2: impact on caregiver role. When asked about their role, there were two distinct groupings: (1) caregivers who were proactive or ‘enabling’ in supporting self-management activities and (2) caregivers who believed the locus of control for self-management should be with the cared-for person. As a result of the REACH-HF intervention, some caregivers adopted a more supportive role using the advice in the ‘Family and Friends Resource’ to discuss how the person was feeling and then agree a mutual management plan.

Informed vigilance. Most caregivers also spoke of the importance of knowing the individual and looked for facial clues such as pallor and dullness of eyes. Vigilance was often reported as a constant covert activity that could be enhanced by REACH-HF.

Because, with the heart failure manual it tells you what to look out for. When you first have got heart failure you don't know what to look out for. It's that you've got no signs, you've got no reference, but with the manual there is that little bit of reference there that says, this is what you need to do. You need to seek medical attention ASAP. Basically that's what it's telling you.

(Female caregiver – wife, aged 41)

Relationship with cared-for person. The intervention was more effective when the couple appeared to have an open honest relationship about the impact of HF, its management and outlook for the future. Two of the adult children reported role reversal making the encouragement of self-management activities difficult.

Supporting physical activity. The REACH-HF walking programme was seen as an opportunity to get out socially, as well as to get some exercise for those caregivers who walked with the cared-for person. At 12 months, the minority who had experienced a significant health setback for the cared-for person, spoke confidently of restarting the exercise programme.

It's given me a pathway to take her down. And, as far as I'm concerned, your programme, it gave me something to do at the time it was needed, but it has also given me something I can do in the future. So your programme is brilliant because it..., has given us a way forward and an improving way forward for when it happened. And now we've got the resources that, already on hand that we know, that we can use again, time and time as required.

(Female caregiver – friend, aged 68)

Supporting emotional and stress management. Those caregivers who had an open relationship or reported getting closer were also more likely to support each other emotionally.

Supporting medication management. Many caregivers read the medication sections of the manual and there was evidence of learning about side effects, dietary interactions, preventing flu and over the counter remedies.

I didn't actually know that he shouldn't really be having spinach and green leafy vegetables, because they're blood thinners and don't go with the warfarin. I don't think I'd ever been told that before, so that was something that I didn't know. And things like when to... When you really should be contacting the heart nurse or the surgery and when you can try to do things yourself, like taking an extra Furosemide, if needed.

(Female caregiver – wife, aged 65)

Impact on caregiver health. There was a strong link between the health of the caregiver and the health of the HF patient. However, caregivers made few changes to management of their own health.

I've always, well I joined the gym when I retired anyway, you know, but you go into these phases where you're going or not. And I stopped going because [husband] wasn't all that well and my daughters had said to me, 'Mum, you've got to start doing things for yourself.' So, sort of, you know, encouraged by them and then I thought, 'Right, this [resource], It's almost like gives you permission, like it's okay to do this.'

(Female caregiver – wife, aged 64)

Discussion

We report the impact on caregivers of REACH-HF – a novel, home-based, self-management intervention aimed at both HF patients and their caregivers. Compared to control, there was no significant difference in caregiver outcome with exception of CC-SCHFI confidence score. However, our qualitative research showed that most caregivers who received the REACH-HF intervention, made positive changes to how they supported the HF patient

they were caring for, and perceived that they had increased their confidence in the caregiver role.

Our findings provide important evidence of the impact of a rehabilitation and self-management intervention for HF patients on caregiver outcomes. We know of only one previous randomized trial that was undertaken in a single centre UK setting. Witham et al assessed a 24-week exercise-based CR intervention in functionally impaired elderly (≥ 70 years) HF patients.²³ Compared to no exercise control, the authors reported no significant difference at 8 or 24 weeks in either patient or caregiver outcomes. Caregiver outcomes collected were similar to the present study, i.e. mental wellbeing (HADS anxiety and depression) and burden/strain (Zarit Burden Interview). Whilst the Witham trial encouraged caregivers to involve themselves in the exercise training sessions of patients, there was no mention of involvement of caregivers in the intervention development or delivery (only 10/71 caregivers in the trial accepted the invitation to participate in the exercise programme). In contrast, the REACH-HF intervention was co-designed with several stakeholders, including caregivers, and included a formal element of the intervention ('family and friends resource') specifically aimed at caregivers.

Strengths of this study included its multicentre design, collection of a range of questionnaire-based outcomes intended to assess mental wellbeing, burden and HRQoL of caregivers, and the mixed methods design that included in depth interviews with caregivers. However, this study has some important limitations that may explain the lack of quantitative differences between the intervention and control groups. First, baseline mean HADS depression, Fam-QoL and CBQ-HF scores indicated consistently good levels of caregiver functioning and, therefore, little room for further improvement. Second, caregivers were not themselves randomized to intervention and control groups, increasing the risk of selection bias and confounding in the comparison of REACH-HF and control groups. Third, given the primary aim of the trial was to assess the impact of REACH-HF on HF patients, the study sample size was powered on the between-group difference in patient rather than for caregivers. For example, if we had powered the trial based on detection of a minimum clinically important difference for the HADS score of 1.4 would have required a sample size of 227 caregivers per group (at 90% power and 5% alpha).²⁴ As this minimum clinically important difference lies well inside the 95% CI for the between-group difference in HADS anxiety and HADS depression seen in the current study at 12 months, we cannot rule out a clinically important effect of REACH-HF intervention upon caregivers. Finally, our trial process evaluation found that healthcare staff facilitating the REACH-HF intervention appeared to be less effective in involving of caregivers than patients.

There is a growing interest in including caregivers in intervention delivery.²⁻⁴ One of the key implications of this

study is the need to better engage caregivers in rehabilitation and self-management interventions for HF patients. We recognize that actively working with caregivers may have been a new experience for many of the healthcare facilitators who participated in this trial and we are currently making adaptations to reflect this in our REACH-HF facilitator training. A structured caregiver assessment tool may assist facilitators to plan and deliver this aspect of the intervention.¹² Further high quality evidence is required to confirm the benefits of actively involving caregivers in the development and delivery of rehabilitation and self-management interventions for HF and other chronic diseases.

Implications for practice

- There are few evidence-based interventions to support caregivers for people with chronic disease.
- Provision of the Rehabilitation Enablement in Chronic Heart Failure (REACH-HF) intervention for caregivers of patients with heart failure may improve their confidence to support self-management and was perceived to be helpful in maintaining their role as caregivers.
- Refinements of the REACH-HF intervention have been made ahead of its roll out into the UK National Health Service, including strategies to better target caregivers.

Acknowledgements

We thank all caregivers, patients, facilitators and clinicians involved in the trial and acknowledge the vital contributions of trial researchers and administrators in Birmingham, Cornwall, Gwent, the Heart Manual Office (Dr Carolyn Deighan and Jenny Edwards for the facilitator training), the Peninsula Clinical Trials Unit, the Royal Cornwall Hospitals Trust (Research, Development and Innovation and Clinical Chemistry departments), the Programme/Trial Steering Committee (Martin Cowie (chair), Graham Dunn, Suzanna Hardman, Roger Boyle, and Liz Clark) and the Data Monitoring Committee (Ann Dorthe-Zwisler (chair), Alan Montgomery, and Gill Furze). We thank Jemma Lough for help with technical editing of the manuscript and Dr Lucy Moore for conducting three of the caregiver interviews.

Declaration of Conflicting Interests

The authors declare that there are no conflicts of interest.

Funding

This work was supported by the National Institute for Health Research (NIHR) under its Programme Grants for Applied Research scheme (grant number RP-PG-1210-12004). KJ is part funded by the NIHR Collaboration for Leadership and Health Research (CLAHRC) and Care West Midlands and NB and RST are both part-funded by the NIHR CLAHRC for the south west peninsula.

Supplemental material

Supplemental material for this article is available online.

References

1. Conrad NA, Judge JTH, Mohseni D, et al. Temporal trends and patterns in heart failure incidence: a population-based study of 4 million individuals. *Lancet* 2018; 391: 572–580.
2. Al-Janabi HJ, Nicholls J and Oyeboode J. The need to “carer proof” healthcare decisions. *BMJ* 2016; 352: i1651.
3. Buck HG, Harkness K, Wion R, et al. Caregivers’ contributions to heart failure self-care: a systematic review. *Eur J Cardiovasc Nurs* 2015; 14: 79–89.
4. Wingham J, Frost J, Britten N, et al. Needs of caregivers in heart failure management: a qualitative study. *Chronic Illn* 2015; 11: 304–319.
5. Wingham J., Frost J and Britten N. Behind the smile: qualitative study of caregivers’ anguish and management responses while caring for someone living with heart failure. *BMJ Open* 2017;7: e014126.
6. Buck HG, Stromberg A, Chung LM, et al. A systematic review of heart failure dyadic self-care interventions focusing on intervention components, contexts, and outcomes. *Int J Nursing Studies* 2017; 77: 232–242.
7. Trivedi RC, Slightam C, Fan VS, et al. A couples’ based self-management program for heart failure: results of a feasibility study. *Front Public Health* 2016; 4: 171.
8. Srisuk NJ, Cameron J, Ski CF, et al. Randomized controlled trial of family-based education for patients with heart failure and their carers. *J Adv Nursing* 2017; 73: 857–870.
9. Greenhalgh T, A’Court C and Shaw S. Understanding heart failure; explaining telehealth – a hermeneutic systematic review. *BMC Cardiovasc Disorders* 2017; 17: 156.
10. Anderson L, Sharp GA, Norton RJ, et al. Home-based versus centre-based cardiac rehabilitation. *Cochrane Database Syst Rev* 2017; 6: CD007130.
11. Schopfer DW, Krishnamurthi N, Shen H, et al. Association of Veterans Health Administration home-based programs with access to and participation in cardiac rehabilitation. *JAMA Intern Med* 2018; 178: 715–717.
12. Taylor RS, Hayward C, Eyre V, et al. Clinical effectiveness and cost-effectiveness of the Rehabilitation Enablement in Chronic Heart Failure (REACH-HF) facilitated self-care rehabilitation intervention in heart failure patients and caregivers: rationale and protocol for a multicentre randomised controlled trial. *BMJ Open* 2015; 5: e009994.
13. Wingham J, Harding G, Britten N, et al. Heart failure patients’ attitudes, beliefs, expectations and experiences of self-management strategies: a qualitative synthesis. *Chronic Illn* 2014; 10: 135–154.
14. Greaves CJ, Wingham J, Deighan C, et al. Optimising self-care support for people with heart failure and their caregivers: development of the Rehabilitation Enablement in Chronic Heart Failure (REACH-HF) intervention using intervention mapping. *Pilot Feasibility Stud* 2016; 2: 1–17.
15. Dalal HM, Taylor RS, Jolly K, et al. The effects and costs of home-based rehabilitation for heart failure with reduced ejection fraction: the REACH-HF multicentre

- randomized controlled trial. *Eur J Prev Cardiol* 2019; 26: 262–272.
16. Taylor RS, Sadler S, Dalal HM, et al. The cost effectiveness of REACH-HF and home-based cardiac rehabilitation in the treatment of heart failure with reduced ejection fraction: a decision model-based analysis. *Eur J Prev Cardiol*. Epub ahead of print 18 March 2019. DOI: 10.1177/2047487319833507.
 17. Zigmond A and Snaith R. The Hospital Anxiety and Depression Scale. *Acta Psychiat Scand*. 1983; 67: 361–370.
 18. EuroQoL Group. EuroQol – a new facility for the measurement of health-related quality of life. *Health Policy* 1990; 16: 199–208.
 19. Nauser JA., Bakas T and Welch JL. A new instrument to measure quality of life of heart failure family caregivers. *J Cardiovasc Nurs* 2011; 26: 53–64
 20. Humphrey L, Kulich K, Deschaseaux C, et al. The Caregiver Burden Questionnaire for Heart Failure (CBQ-HF): face and content validity. *Health Qual Life Outcomes*. 2013;11: 84.
 21. Vellone E, Riegel B, Cocchieri A, et al. C. Validity and reliability of the caregiver contribution to self-care of heart failure index. *J Cardiovasc Nurs* 2013; 28: 245–255.
 22. Braun V and Clark V. Using thematic analysis in psychology. *Qual Res Psychol* 2006; 2: 77–101.
 23. Witham MD, Fulton RL, Greig CA, et al. Efficacy and cost of an exercise program for functionally impaired older patients with heart failure: a randomized controlled trial. *Circ Heart Fail* 2012; 5: 209–216.
 24. Puhan MA, Frey M, Büchi S, et al. The minimal important difference of the hospital anxiety and depression scale in patients with chronic obstructive pulmonary disease. *Health Qual Life Outcomes* 2008; 6: 46.